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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO.
09/828,574	04/06/2001	Salvatore Albani	UCSD1310-1	6601

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EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 06/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/828,574	Albani et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-59 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-59 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s).
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) ☐ Other:

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24 and 33-42, drawn to peptides, classified in class 530, subclass 300.

II. Claims 25-27 and 31-32, drawn to DNA, classified in class 536, subclass 23.7.

III. Claims 28-30, drawn to antibodies, classified in class 530, subclass 387.1.

IV. Claims 43-51, drawn to methods of treating immune-mediated disease, classified in class 424, subclass 184.1.

V. Claims 52-59, drawn to methods of modulating an immune response, classified in class 514, subclass 2.

Additionally, as set forth in MPEP 803.04 molecules with separate sequences are separate inventions. Consequently, Applicant's are restricted to a single sequence. Note, a substitution of a sequence is a separate sequence. Furthermore, the claims are restricted to a single kind of heat shock protein, i.e., mycobacterium hsp60, mycobacterium hsp65, mammalian heat shock protein are all proteins with a distinct primary, secondary, and tertiary structure. Consequently Applicant's are restricted to a single kind of protein and a single sequence. Applicant's are required to identify which claims encompass the elected sequence.

It is noted that claim 30 recites the method of claim 28, however claim 28 is not a method, this claim has been grouped with the antibody claim upon which it depends. If Applicant's intended a method, this claim will be a distinct group.

Should Applicant's elect Groups IV or V, Applicant's are further restricted to a single disease or immune response type for treatment. For instance treatment of MS, rheumatoid arthritis, lupus, type I diabetes, scleroderma, myasthenia gravis, ulcerative colitis, melanoma, leukemia, lymphoma, lung, liver, kidney, brain, bladder, retinoblastoma, sarcoma and connective tissue cancers, each require selection of a patient with different symptoms and etiological agents. Consequently treatment of each of these disorders requires a separate search and consideration.

2. The inventions are distinct, each from the other because of the following reasons:

Invention I drawn to peptides, and Invention II drawn to nucleic acids are distinct since they are products with different structure and biological properties. The protein is made of amino acids whereas the nucleic acid molecule consists of nucleotides. Further methods known in the art used to make the polypeptide require different reagents and parameters from the methods of making nucleic acid encoding the protein and the method of making the polypeptide does not require the nucleic acid. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography.

Invention III drawn to an antibody is distinct from Inventions I-II and IV-V, since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing.

Invention IV, drawn to methods of treatment, is distinct from Inventions I-III, and V, since it requires selection of individuals for the treatment of a specific condition.

Invention V, drawn to methods of modulating an immune response, is distinct from Inventions I-IV, since it requires additional biological reagents and parameters for determining in vivo efficacy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225.

Mark Navarro

Primary Examiner

June 20, 2002